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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/605,521	06/27/2000	Gloria M. Coruzzi	5914-083-999	5147

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EXAMINER	
ZARA, JANE J	

ART UNIT	PAPER NUMBER
1635	9

DATE MAILED: 12/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary

Application No.	Applicant(s)
09/605,521	Coruzzi et al
Examiner	**Art Unit**
Jane Zara	1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Oct 3, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *8-10, 14, 15, and 21-26* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *8-10, 14, 15, and 21-26* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 8-10, 14-15, 21-26 are pending in the instant application.

Election/Restriction

Applicant's election of Group II in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The amendment filed on October 3, 2002 in response to the election requirement mailed July 3, 2002 has been acknowledged. Applicant timely addressed the restriction (election) requirement in Paper No. 7.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 10, 14, 15 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 comprises two independent sentences. Appropriate clarification is requested (i.e. perhaps inserting --wherein-- after the comma in line 1?).

In claim 26, line 1, the term "transgennic" is unclear. Appropriate correction is requested.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-10, 14, 15, 21-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transgenic plants comprising a transfected gene encoding either glutamine synthase (GS) or aspartate synthetase (AS), does not reasonably provide enablement for transgenic plants comprising a transfected gene encoding aspartate aminotransferase, glutamate 2-oxoglutarate aminotransferase, glutamate dehydrogenase or asparaginase, whereby ectopic expression of such a transfected gene imparts faster or greater growth characteristics, or imparts increased amino acid or nitrogen content, compared to non-transfected plants The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to transgenic plants comprising a transfected gene encoding aspartate aminotransferase, glutamate 2-oxoglutarate aminotransferase, glutamate dehydrogenase or asparaginase, whereby ectopic expression of such a transfected gene imparts faster or greater growth characteristics compared to non-transfected plants, or imparts increased amino acid or nitrogen content compared to non-transfected plants. The claims are also drawn to the generation of a chimeric, bifunctional glutamate 2-oxoglutarate aminotransferase enzyme.

The following factors have been considered in determining that the specification does not enable the skilled artisan to make and/or use the invention over the scope claimed.

The state of the prior art and the predictability or unpredictability of the art. The following references document the unpredictability that has been reported for the expression of recombinant nucleic acids encoding nitrogen assimilation enzymes in transgenic plants. Eckes et al (reference "AM" of IDS filed October 3, 2002, Paper No. 8) found overexpression of a nitrogen assimilation enzyme, glutamine synthase (GS) had occurred in transgenic plants, but without any accompanying phenotypic changes that were expected to be associated with GS overexpression, such as increased growth in the transgenic plants (See especially third full paragraph on page 266). Temple et al (reference "BM") found that plants transfected with recombinant GS did not exhibit increased GS enzymatic activity, suggesting that post-translational assembly of GS subunits into a functional holoenzyme requires additional factor(s) and is under regulatory control (See especially the abstract and third full paragraph on page 319). Hirel et al (reference "AU") found an unpredictable and altered subcellular localization of transfected GS in transgenic plants compared to endogenous GS (See especially the abstract, last paragraph on page 214- all of text on page 215). Hemon et al (reference "AS") surprisingly found a lack of correlation between the accumulation of expressed recombinant GS in transfected plants compared to in vitro plantlets, observing that the transfected plants displayed altered abilities to assemble active isoenzymes in various organelles, and that recombinant enzymes had altered solubility properties (i.e. aggregation problems) compared to endogenous enzyme (See

especially the abstract, text on page 903). In addition, both Napoli et al (reference "BC") and Jorgensen found gene silencing in transgenic plants following transfection with recombinant, homologous genes (See both documents in their entirety).

The amount of direction or guidance presented in the specification AND the presence or absence of working examples. Applicants have not provided guidance in the specification toward a method of generating transgenic plants with increased growth, nitrogen or amino acid content comprising the transfection of recombinant nucleic acids encoding the nitrogen assimilation/metabolism enzymes selected from the group consisting of aspartate aminotransferase, glutamate 2-oxoglutarate aminotransferase, glutamate dehydrogenase or asparaginase. The specification teaches the generation of transgenic plants comprising the transfection of recombinant nucleic acids encoding glutamine synthase (GS) and aspartate synthetase (AS), whereby the transgenic plants display altered nitrogen assimilation properties, but which transgenic plants were found to grow more poorly than non-transformed plants. The specification fails to teach the generation of transgenic plants with increased growth, nitrogen or amino acid content comprising the transfection of recombinant nucleic acids encoding the nitrogen assimilation/metabolism enzymes selected from the group consisting of aspartate aminotransferase, glutamate 2-oxoglutarate aminotransferase, glutamate dehydrogenase or asparaginase. The specification furthermore fails to teach the generation of a chimeric bifunctional glutamate 2-oxoglutarate aminotransferase enzyme. One skilled in the art would not

accept on its face the examples given in the specification of the transfection of GS or AS into plants, producing transgenic plants which grow more slowly than non-transformed plants, as being correlative or representative of the successful generation of transgenic plants with improved growth characteristics, or increased amino acid and/or nitrogen content following the transfection of nucleic acids encoding aspartate aminotransferase, glutamate 2-oxoglutarate aminotransferase, glutamate dehydrogenase or asparaginase, in view of the lack of guidance in the specification and known unpredictability associated with generating a desired phenotype upon transfection of recombinant nitrogen assimilation/metabolism enzymes into plants. The specification as filed fails to provide any particular guidance which resolves the known unpredictability in the art associated with the proper subunit assembly, organelle or subcellular targeting and functional expression of ectopically expressed, recombinant nitrogen assimilation/metabolism enzymes.

The breadth of the claims and the quantity of experimentation required. The breadth of the claims is very broad. The claims are drawn to transgenic plants comprising a recombinant, ectopically expressed gene encoding aspartate aminotransferase, glutamate 2-oxoglutarate aminotransferase, glutamate dehydrogenase or asparaginase, whereby ectopic expression of such a transfected gene imparts faster or greater growth characteristics compared to non-transfected plants, or imparts increased amino acid or nitrogen content compared to non-transfected plants. The claims are also drawn to the generation of a chimeric, bifunctional glutamate 2-oxoglutarate aminotransferase. The quantity of experimentation required to practice

the invention as claimed would require the *de novo* determination of the phenotypes associated with transgenic plants comprising any of the recombinant nitrogen assimilation/metabolism enzymes selected from aspartate aminotransferase, glutamate 2-oxoglutarate aminotransferase, glutamate dehydrogenase or asparaginase, whereby ectopic expression of such a transfected gene imparts faster or greater growth characteristics compared to non-transfected plants, or imparts increased amino acid or nitrogen content compared to non-transfected plants. Since the specification fails to provide any particular guidance for the generation of transgenic plants comprising any of these nitrogen assimilation/metabolism genes, and since determination of the factors required for successfully and appropriately expressing these recombinant enzymes in a transgenic plant, and further whereby faster or greater growth characteristics are displayed in the transgenic plants compared to non-transfected plants, or increased amino acid or nitrogen content is displayed in transgenic plants compared to non-transfected plants, or a chimeric bifunctional glutamate 2-oxoglutarate aminotransferase has been generated, it would require undue experimentation to practice the invention over the broad scope claimed.

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Lacomciere

KAREN LACOMCIERE
PATENT EXAMINER

JZ

November 27, 2002